Jackson Heart Study Protocol

Manual 12

Quality Control Manual

Version 1.1

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides background, organization, and general objectives of the JHS Study. Manual 2 describes all components and procedures carried out with the JHS cohort. Manual 3 provides detailed information about the Family Study that is embedded in the JHS cohort. Detailed Manuals of Operation for specific procedures, including those or reading centers and central laboratories, make up Manuals 4 through 9 and 11. Manual 12 provides the framework for quality assurance and quality control. Manual 13 and 14, currently under development, will describe Community Partnership activities and operations of the Undergraduate Training Center respectively. Manual 15 provides procedures for the time period between the end of the baseline clinical examination and the initiation of the second clinical examination.

JHS Study Protocols and Manuals of Operation

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6.	Echocardiography
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1.0 INTRODUCTION

The distinction between quality assurance and quality control is both arbitrary and philosophical. Quality assurance includes activities that are designed to assure quality of data, which take place prior to collection of data. Quality control, on the other hand, relates more to efforts during the study to monitor the quality of data at identified points in the collection and processing of data. This manual focuses primarily on quality control, whereas quality assurance is the essence of the entire Manual of Operations, and includes the following activities:

1. Detailed protocol development. A clear description of the study design, training, certification, and the various data collection activities provides the blueprint for the study. Each protocol is a written reference for staff and researchers. Procedures for handling the routine, as well as the exceptional, are given. Those protocols constitute the JHS Manuals of Operation.

2. Training and updating training. Training is the transfer of the study plans in the protocol to the research staff. The process has resulted in clarification and revision of the protocol. Special materials for this purpose have been developed for JHS and are the basis for continuing education during the study. Continued investment in quality data during the study is made by periodic refresher training sessions, which review the protocol and update personnel on any changes, which have occurred.

3. Certification. Criteria to examine the adequacy of an individual's training have been established. Individuals meeting these criteria are qualified to execute a protocol or a segment of it. Certification and periodic re-certification indicate that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center monitors the study to ensure that staff performs only those functions for which they are certified and that re-certification activities are implemented as planned and as scheduled.

For quality control purposes, JHS data collection and transfer is monitored by observation (directly and by tape recording) and by quantitative assessment using both specific quality control procedures (e.g., repeat measurements) and statistical analysis of study data for quality control (QC) purposes. Monitoring is performed both by personnel within the field centers and by monitoring visits from the Coordinating Center and various central agencies. A summary of selected aspects of JHS Cohort Study quality control follows.

1. Observation monitoring. Over-the-shoulder observations of staff by supervisors or those who wrote the protocols identify techniques that need improvement and points where the protocol is not understood. Also, periodic monitoring visits are made to each field center by Coordinating Center staff to observe actual clinic activities. Detailed checklists are used to assess strict adherence to protocol. Immediate feedback is given, and general recommendations for improvements are sent to the Steering Committee for action. Another form of observation in the JHS study takes place with the interview portion of the protocol. A Coordinator Center supervisor reviews the tapes on a random basis, reviewing at least one of each type per month. The supervisor checks for adherence to protocol and for accuracy of recorded responses. The Director of Recruitment conducts weekly over-the-shoulder observation of recruiters in the field. Three recruiters are randomly selected for each week. In addition to field observation of the recruiters, the Director of Recruitment conducts weekly phone calls to a random subset of participants to obtain feedback on their recruitment experience. The subset of participants chosen is from the pool of participants interviewed by the recruiters who are not chosen for field observation that week. The data collection instruments for field observation and phone calls to participants are in Appendix II.

2. Quantitative monitoring. Random repeated measurement by the same and by different technicians are used as quality control tools. There are two important benefits from random repeat measurements. First, randomly re-doing a fraction of an individual's work. is likely to stimulate a better overall quality of data. Second, the duplicate determinations provide measurements of data quality. At the time of reporting the results of the study, it is important to establish that the "error" in the data is not so large as to threaten the validity of conclusions. Actual study data are useful to monitor quality of performance. Mean and standard deviations of

study variables, by technician, are monitored for differences among technicians or trends over time. Digit preference in anthropometry or blood pressure measurement is monitored with study data.

3. Reporting results. Two aspects of the reporting of quality control monitoring should be emphasized. First, the results must be timely. When remedial action is required, reporting must be prompt so that a return to an acceptable level of performance is not unnecessarily delayed. Second, the reporting format must be easily understood. Tabular presentations are accompanied by clear graphical displays.

4. Action on results. With conscientious and trained staff, quality control reports provide an opportunity to praise a job well done. On the other hand, a poor performance is the basis for some remedial action. Depending upon past performance, the amount of error, and, taking due account of personal circumstances, the appropriate action may be a simple discussion to encourage a better performance. Re-training may also be appropriate at times.

1.1 Monitoring of Data Quality and Implementing Corrective Action

The subsequent sections of this manual describe the procedures and reports used to monitor quality control of the JHS Study. These reports are designed to be clearly understandable, to be distributed to individuals responsible for reading them carefully, and to lead to corrective actions. The JHS Statistics, Sampling and Quality Control Committee (SSQC) is the designated committee to coordinate and direct the quality control activities. The SSQC is charged with the responsibility to review all reports with specific attention given to deviation from protocol, recurrent problems and trends or shifts in data over time. The QC Workgroup of the SSQC may be charged to study and provide recommendations for specific QC needs of the study. The SSQC prepares recommendations to the Steering Committee in matters of quality assurance, and contacts the Examination Center, Reading Centers, or laboratories as needed, to advise them of a problem and to discuss the mechanism for correction, central logs of data and management quality problem are reviewed by the SSQC.

The role of the JHS Coordinating Center in quality assurance and control is described later in this manual. More specifically, as the repository for JHS Study data, the Coordinating Center is responsible for preparation and dissemination of QC reports. These reports consist of tabulated data and summary statistics, and identify specific QC problem. The JHS Coordinating Center, via its CC-EC liaison, maintains contact with the EC to confirm that it has been notified of a problem and that corrective action has been implemented. The Coordinating Center maintains central logs of data quality problem and solutions. The Coordinating Center conducts periodic Examination Center monitoring during which Coordinating Center staff participate in and observe a routine JHS clinic visit. In response to requests from the SSQC, the Coordinating Center replicates pertinent sections of quality control reports prepared by reading centers/laboratories. Some external quality control programs for the reading centers/laboratories are administered by the CC, and reported to the SSQC.

The distribution of the QC reports and the designation of persons or groups responsible for responding to the reports and implementing corrective action are described below. The EC and/or reading centers are given the responsibility of reading, implementing corrective action, and responding to the reports in their respective area. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the SSQC. Immediate QC problem identified by reading centers, laboratories or the Coordinating Center (e.g., data entry problems, broken vials, unacceptable pulmonary function tests) should be sent to the appropriate centers including the Examination Center directly for correction with a record kept by the Reading Center/laboratory/Coordinating Center. Problems identified by periodic monitoring are sent to the Examination Center/Reading Centers/laboratories with concurrent monitoring by the SSQC. The distribution of periodic reports described latter in this manual is as follows:

1. QC reports on technician-specific performance are sent quickly to the Examination Center Principal Investigators, (PI) and the SSQC within a week of generating the report.

2. QC reports on laboratories/reading centers' performance is sent quickly to the respective principal investigators, and to the SSQC within a week of generating the report.

3. Summary QC reports without technician-specific data are sent to the Steering Committee through the SSQC. The following centers and committees have responsibility for responding to the reports as follows:

    a) Examination Center PIs, study coordinators, local certifiers/trainers. Review each QC and monitoring report with technician-specific quality; identify a solution to each problem; implement corrective action; report corrective action to Coordinating Center monitor.
    b) PI of laboratories and Reading Centers Directors. Review each QC and monitoring report for their laboratory/center; identify a solution to each problem; implement corrective action; report corrective action to SSQC.
    c) Statistics, Sampling and Quality Control Committee (SSQC). Review each QC and monitoring report with attention to deviation from protocol, recurrent technician or field center problems and temporal trends; direct field center/reading center/laboratory attention to problem and recommend additional corrective action if they persist; monitor the implementation of corrective action; contact and coordinate study agencies and investigators to review data quality problem and solutions; prepare summary reports and recommendations for the Steering Committee.
    d) Steering Committee. Review QC summary reports; monitor data quality trends; direct the QCC in areas needing special attention; responsible for changes in protocol.

Table 1: SCHEDULE OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

Procedure	Quality Assurance or Quality Control	Monitoring Methods	Responsible	Frequency	Written Report to CC & SSQC
HII Interviews	QA QC	Weekly Monitoring – observation (5% of interviews)	Director of Recruitment	Weekly	Yes
Data:					
Data	QC (Data Entry)	Completeness & integrity of data	CC	Weekly	No
	QA (Transmittal)	Completeness & integrity of data	CC	Monthly	No
Cohort Procedure:					
• Interviewer-administrated forms for re-certification	QA	Content analysis of taped interviews; and by observation.	Clinic Manager & CC/EC Liaison	Yearly	No
Clinic	QA (Procedures)	Observation	Clinic Manager	Weekly	No
	QC (Interviews)	Monitoring - Observation	Clinic Manager	Weekly	No
Protocol adherence & interviewing techniques	QA	Monitoring of examinations	CC	Annual	Yes
Measuring Tapes	QA Equipment Validation	Checked for damage	Clinic Staff	Weekly	No
Scales	QA Equipment Validation	Zero balanced/calibrated	Clinic Staff	Daily/weekly	No
Sitting Blood Pressure	QA **Equipment Maintenance**	Recording of all checks, problems and maintenance	Clinic Staff	Daily	No
	QC	Adjusted means of BP data Re-certification of technicians	CC	Quarterly Semi-annually	Yes
Sphygmomanometers	QA **Equipment Maintenance**	Random zero inspection Standardization of manometer	Clinic Staff	Weekly Monthly	No No
Ankle/Brachial	QA **Protocol**	Training & certification	ABP RC	Annual	
	QC	Adjusted means of BP data Re-certification of technicians	CC	Quarterly Semi-annually	Yes
Blood Analysis Lab	QA **Equipment Maintenance**	Check Freezer Temp, refrigerator & centrifuge(s)	Clinic Staff	Daily	No

Table 1 (Cont'd): Schedule of Quality Assurance and Quality Control Activities

Procedure	Quality Assurance or Quality Control	Monitoring Methods	Responsible	Frequency	Written Report to CC & SSQC
Blood Analysis Lab	QC	Condition of arrival completion rate of GTTs; Means & SDs	Lab & CC	Monthly	Yes
ECG	QC	Condition on arrival; quality grades by tech; % tech over reading; % missing data	Reading Center & CC	Monthly	Yes
ECHO	QC	Condition on arrival; quality grades by tech; % tech over reading; means & SDs (selected measurements)	Reading Center & CC	Monthly	Yes
Ultrasound	QC	Condition on arrival; quality grades by tech; % tech over reading; means & SDs (selected measurements)	Reading Center & CC	Monthly	Yes
Pulmonary Function:	QA Spirometer **Equipment Maintenance**	➢ Leak, volume check ➢ Distilled H_2O, chart speed & linearity checks	Clinic Staff	➢ Daily ➢ Weekly	➢ No ➢ No
	QC	Condition on arrival; quality grades by tech; means & SDs (selected measurements)	Reading Center & CC	Monthly	Yes
Medical data review	QA	Done in accordance to JHS Protocol	EC PI	Unspecified	No
Referrals & results reporting	QA	Done in accordance to JHS Protocol	EC PI	Unspecified	No
Family Study:					
• Pedigrees	QA	Check for structural errors	CC	Monthly	No
• DNA & blood samples	QA	Check processing & storage procedures	CC/Howard University	Monthly	No
• Genotype	QA	Check for maker-typing incompatibilities	Howard University	Quarterly	Yes
24^{o} Ambulatory BP	QA **Equipment Maintenance**	Using the Grey Area Decision Tree	Clinic Staff	Monthly	No Performance Checklist
Diet:	QA	➢ Certification ➢ Review of Taped interviews	Tufts	➢ Ongoing ➢ Monthly	➢ Yes ➢ No
Physical Activity:	QA	➢ Certification ➢ Review of Taped interviews	Tufts	➢ Ongoing ➢ Monthly	➢ Yes ➢ No

2.0 OPERATION OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

2.1 QA monitoring process for Recruitment

There will be ongoing evaluation of Recruiters to ensure quality assurance of protocols being followed during the recruitment interview process. For quality purposes each Recruiter is monitored per observation and random telephone follow-up with participants. The QA monitoring will be done by the Director of Recruitment.

In order to monitor 5% of the average number of home induction interviews completed, three Recruiters per week will be randomly selected by the Coordinating Center. Field observations will be done by the Director to determine if quality assurance protocols are being followed. The remaining Recruiters for that week will be monitored via telephone follow-up with participants. A checklist will be used to determine satisfactory performance. (see appendix I) Random selection will be done on a rotating cycle to monitor all Recruiters in an ongoing manner.

2.2 Interviews in the Baseline Exam Visit

With participant approval, most interviewer-administered forms are taped for quality control. A non-systematic sample of forms is reviewed by the Clinic Manager and interviewer team leader monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence and interviewing techniques are reviewed at least biannually by Coordinating Center examination monitors. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Clinic Operations Committee. Data quality is monitored by the Statistics, Sampling and Quality Control Committee quarterly.

The Coordinating Center liaison to the Examination Center (CC/EC liaison) will log and archive all taped interviews on a monthly basis. He/she will also review a subset of the taped interviews. The Coordinating Center liaison to the Examination Center will review a subset of the Home Induction Interview Forms (HII) monthly. The Coordinating Center liaison will provide written feedback to the interviewer via the Director of Recruitment. The EC/CC liaison will provide written feedback to the interviewer via the Clinic Manager. A copy of the communication will be filed in the Coordinating Center.

Though the Examination Center PI is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the JHS protocol, the Coordinating Center liaison will be responsible for conducting a random exit interview with participants related to medical data review and referrals. In terms of reports, the Coordinating Center will perform bimonthly an analysis on the LEI form to determine which participants have or have not received their results. The analysis will also entail descriptive statistics on duration from clinic visit to mailing of participant's results report.

2.3 Quality Assurance for Cohort Procedures

There will be ongoing evaluations of clinic staff to ensure quality assurance of protocols being followed in the clinic. For quality purposes each staff is monitored per cohort procedure by the Clinic Manager yearly for re-certification purposes.

On a monthly basis, three staff members are selected randomly for observations to determine quality assurance protocol. The staff person will be observed on two areas of clinic exam component to determine satisfactory performance. This will be done monthly on rotating cycle to complete all staff and continuation of the monitoring will be ongoing. The various cohort procedures will be assessed for a given clinic staff by the Clinic Manager or a designate evaluator on the specific time frame specific in Table 1 of the manual. The corresponding instrument for each procedure is provided in Appendix IV – Evaluation/Certification/Site Visit Checklist. Monitoring of carotid ultrasound and echocardiography will be performed by designated evaluator by the Echocardiography Reading Center (ERC).

The EC/CC liaison will monitor clinic operations using tools in Appendix III of the manual. Review of taped interviews will be done annually and outcomes of the evaluation will be utilized in the recertification of technicians. Monthly the EC/CC liaison will conduct QA checks on equipment maintenance logs for blood pressure, ECHO, ECG, ultrasound and pulmonary function test. Weekly QA monitors involve overall operation of the clinic. Both the clinic manager and the EC/CC liaison will have on file the QA monitoring done in the clinic by the clinic manager, EC/CC liaison and the designated evaluator(s) of technicians responsible for carotid ultrasound and echocardiography imaging.

On a quarterly basis, the EC/CC liaison and the clinic manager will present a brief report on outcome of the QA monitoring highlighting the positives and negatives observed and seek input from the QC committee in terms of corrective action for identified problems if any. These reports will be concise and will not require extensive analysis of the data collected. A similar report will be presented on QA data collected by the Director of Recruitment via phone interview of participants and field monitoring of recruiters.

3.0 DESCRIPTION OF THE QC SYSTEM FOR REPEATED MEASUREMENTS

In several areas, repeated measurements during a clinic examination are taken for quality control purposes and are recorded on study forms separate from the participant's original forms. These forms are designated as belonging to phantom participants. The phantom participants are approximately 5% of assigned study IDs for venipuncture and urine collection. The 5% of the total sample of 6500 participants translated to 325 participants. The sampling of these 325 participants are weighted heavily in the earlier phase of the study and reduced over time once sufficient data has been collected, analyzed and reviewed. Details of sample size and the methodology for carrying out repeated measures for all replicate procedures are given below. The Examination Center with the assistance of the Coordinating Center creates phantom participant folders when needed, and initializes a phantom participant diskette. As a safeguard against gathering unnecessary data on the phantom participant forms, only a subset of the usual study forms is included for QC repeated studies. The data collected on the phantom form is later keyed into CliniTrial. Repeat measurements are then entered, by the technician making the measurements, the phantom forms just as regular study data, as explained below, and the folders are processed as regular study data. There is one extra form in the QC phantom participant's folder, the JHS QC Phantom Participant and Non- Participant ID Form (Appendix 1), which is used to match the phantom ID to the IDs of the JHS participants contributing repeat measurements. This form is also used to record IDs used for data collected on persons who are not JHS study participants (e.g., monitors from the Coordinating Center). This form is sent to the Coordinating Center with a copy kept in the phantom participant's folder. As a further backup, the QC phantom ID is entered on a form in the associated JHS participant's folder, as explained below.

The procedures for using the QC phantom participant folders are:

1) The study coordinator creates phantom folders, putting the QC phantom participant labels on the Phantom Participant Form, the anthropometry form, and the venipuncture form, and places these in the folders. When QC phantom participant IDs are assigned, the person making the assignment does the following on the Quality Control Phantom Participant and Non-Participant ID Form:
    a) Places the label for the ID assigned to the QC phantom in the space provided at the top of the form;
    b) Circles "P" for "A QC Phantom Participant" on the form;
    c) Fills in their own ID and the data the QC phantom ID was assigned in the spaces provided.
2) As JHS participants contribute replicate data, the matching JHS participant labels are affixed to the QC Phantom Participant Log for the data that are contributed. In the case of venipuncture eight replicate QC blood drawing tubes are assigned to a phantom participant. These eight replicate QC blood draws are not from the same individuals. The blood draws are on five individuals whose clinic visits are 2-3 days apart.
3) After all needed repeat measures are recorded on the phantom's forms, or when two weeks have passed since the first QC data were entered on the form, the designated Examination Center staff inserts the folder in the regular stream of participant folders as if the Exit Interview had just

finished. It is processed as usual, except the QC Phantom Participant A designated Examination Center staff will copy the log and place in the folder, with the original sent to the Coordinating Center.

It is desirable to utilize each phantom participant ID for gathering all replicate QC entries in order to use fewer JHS IDs. However, there are times when this should not be maintained. For example, the designated Examination Center staff keeps a reserve of 2-3 phantom participant folders, so that if none is ready to leave the venipuncture station for anthropometric measurements or to have any of the other replicate procedures performed, new folders from the study coordinator are used. Since different measurement groups in anthropometry may be sampled at different rates, the number of IDs needed to record all anthropometry repeats data groups will not be balanced.

When monitors, volunteers or other persons who are not participants in the JHS cohort go through at least some of the JHS examination procedure, they are assigned a JHS cohort ID, which are recorded on the Quality Control Phantom Participant and Non-Participant ID Form. The following procedure should be used:

1) The study coordinator assigns a JHS cohort ID at the start of their visit.
2) As soon as the ID is assigned, a label for that ID is placed in the box marked "Phantom Participant ID Number" on the QC Phantom Participant and Non-Participant ID Form, and "N", for "An ID Used for a Non- Participant" is circled.
3) Also as soon as the ID is assigned, the person making the assignment records the date and their own ID number in the spaces provided.
4) The same week the non-participant is seen, the QC Phantom and Non-Participant ID Form will be photocopied. The copy is retained at the field center, and the original is sent to the JHS Coordinating Center.

Deadlines for sending Phantom Participant and Non-Participant ID forms to the Coordinating Center:

1) Forms filled out to record the IDs used for non-participants in the JHS cohort study should be sent to the Coordinating Center at the end of the same week in which they are collected.
2) For quality control phantoms, the folder for the phantom should go to the study coordinator for routine processing of any Venipuncture or Anthropometry form filled out on a phantom.

3.1 Replicate Clinic Procedures:

The purpose the replicate studies are to ensure that the data collected in the Jackson Heart Study is of quality. Therefore, these replicate studies are a part of the whole quality control plan of the Jackson Heart Study.

The following clinic procedures are included in the replicate studies: Blood/Lipids (venipuncture), Urine, Anthropometry, Blood Pressures (Sitting & Ankle-Brachial) Electrocardiography (ECG), Echocardiography (ECHO), Pulmonary Function Test (PFT) and Carotid Ultrasound. Jackson Heart Study (JHS) participants will not be selected to participate in more than one replicate study, especially those involving ECHO, ECG, PFT, Ultrasound and Ankle-Brachial Blood Pressure test. Participants will receive a Phantom ID for their repeated measure of any given test. The data collected in the replicate studies will be for sole purpose of QC analysis.

For each of the proposed replicate clinic procedures, the Study Plan will entail the following:

- Task (Activities)
- Target Sample (including sample size)
- Selection and Assignment Study units

3.1.1 Study Plan – Venipuncture and Urine:

Task (Activities) – Eight replicate QC blood-drawing tubes will be assigned to a phantom participant. These eight replicate QC blood draws are not from the same individuals. The blood draws are on five individuals whose clinic visits are 2-3 days apart. The urine collection will be on a sixth person other than the five individuals that had blood drawn. The Clinic Manger (or designate) will be given random

selection scheme. For a given clinic day, the scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant and with blood tubes need to be drawn. The scheme will also be used to randomly select a participant for repeated urine collection.

Target Sample – The target sample for this replicate study will be JHS participants. The total sample size for this study is 325 or 5% of the total study sample of 6500.

3.1.2 Study Plan – Anthropometry and Blood Pressures (Sitting & Ankle-Brachial):

Task (Activities) – The following measures listed under selected measures will be repeated on a random selection of JHS participants. Fifty percent of the replicate study participants will have their repeated measures conducted by the same technician and the other 50% by a randomly selected technician. The Clinic Manger (or designate) will be given random selection schemes. One scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant for a given clinic day and whether or not the second measurement will be done by the same technician or by a different technician. The second will assist the Clinic Manager (or designate) to randomly select a second technician for repeated measurement.

Target Sample – The target sample for this replicate study will be JHS participants. The total sample size for this study is 200. This sample size was arrived at using data from JHS participants who had clinic visit between September 2000 and September 2001. In addition to setting the significance level (α) at 5% and a power of 90%, it was assumed that the mean difference of these measures for each pair would not exceed 5%. For anthropometric measures the sample sizes ranged from 140 to 200 for each of the measures. The sample sizes for the blood pressures (sitting and ankle-brachial) ranged from 150 to 200.

Selection & Assignment Study units – Study subjects will be pre-selected at random prior to their clinic visit. Suppose the goal is to select the 200 subjects over 18 months (78 weeks) after the start date then an average of 2.6 ($\cong$ 3) subjects per week will need to be assigned for repeated measures. Hence if three JHS participants are randomly assigned to participate in repeated measures for any of selected anthropometric or blood pressure replicate measures, the will be a resultant sample size of 234 – over sampling of 17%. Hence if a randomly selected participant refuses to participate, there will be no need to replace that individual. This based on the assumption that the refusal rate will be below 17%.

Selected Measures –

Procedures	Measures (Variables)
Anthropometry	Height (ANTA1), Weight (ANTA 2), Girth-Waist (ANTA 3a) & Girth-Neck (ANTA 3b)
Sitting Blood Pressure	Heart Rate (SBPA8), First Systolic BP (SBPA13), First Diastolic BP (SBPA14), First zero reading (SBPA15), Second Systolic BP (SBPA16), Second Diastolic BP (SBPA17) & Second zero reading (SBPA18).
Ankle-Brachial Blood Pressure	Max. Inflation level (ABBA6), Brachial (ABBA7), Right posterior tibia (ABBA8), Left posterior tibia (ABBA9), Left posterior tibia (ABBA10), Right posterior tibia (ABBA11) & Brachial (ABBA12)

3.1.3 Study Plan – Electrocardiography:

Task (Activities) – The replicate study in this case with utilize repeating scans for a random subset of JHS participants. This will not be done routinely but once a year as part of re-certification of ECG technicians. Each technician will have to complete 5 QC scans as part of the re-certification process. Individuals selected for the scan will be done at random. In addition to these yearly QC scans; ECG scans sent in from hospitals (as part of surveillance) can also be evaluated for QC. **There will no re-reads of blinded images because all ECG scans are machine-read.**
Target Sample – The sample size will be 60 participants for the entire recruitment period. This translates to 20 participants per year (5 participants per technician per year).

Selection & Assignment Study units - The Coordinating Center, working in conjunction with the Examination Center and the ECG Reading Center, will design a randomization scheme to carry out this aspect of the ECG replicate study. The study will be designed such that the scans will address inter- and intra-reliability.

3.1.4 Study Plan – Echocardiography:

Task (Activities) – The replicate study in this case will utilize two approaches. One approach hence referred to as Approach I, will involve repeating scans for a random subset of JHS participants. The other approach hence referred to as Approach II, will involve blindly rereading single scans by the same reader or by a different reader.

Approach I***:*** JHS participants will be randomly pre-selected prior to clinic visit to have a second imaging done by either the same technician or by a different technician. In the case of the second imaging done by a different technician, the second technician will also be randomly selected to perform the task.

Approach II***:*** A random selection of single scans will be blindly reread by the same reader or by a different reader. The Coordinating Center working in conjunction with the Examination Center and the Echo Reading Center will design a randomization and blinding scheme to carry out this aspect of the Echo replicate study.

Target Sample –

Approach I***:*** JHS participants are the target sample. A total sample size of 250 participants is proposed. The total sample size of 250 was derived from rough calculations based on studies by Dai et. al *(Hypertension. 1999;34:236-241),* Thomson et. al. *(J Am Coll Cardiol 2001;38: 867-75),* and Collins et. al. *(J Am Coll Cardiol 1989 Sept; 14(3):672-6)* . Since there are four Echo technicians, there four ways of obtaining repeated measures by the same technician (25 participants per technician) and six ways of obtaining repeated measures by a different technician (25 participants per technician).

Approach II**:** The sample units in this case are the single images of JHS participants. A total of 326 images (5% of total JHS sample) will be randomly selected for this aspect of the study. The same reader will blindly reread 50% (163) of the total sample other 50% by a different reader.

Selection & Assignment Study units -

Approach I***:*** The Clinic Manger (or designate) will be given random selection schemes. One scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant for a given clinic day and whether or not the second measurement will be done by the same technician or by a different technician. The second will assist the clinic manager (or designate) to randomly select a second technician for repeated measurement.

Approach II*:* The Coordinating Center working in conjunction with the Examination Center and the Echo Reading Center will design a randomization and blinding scheme to carry out this aspect of the Echo replicate study.

3.1.5 Study Plan – Pulmonary Function Test:

Task (Activities) – The complete test will be performed.

Target Sample – JHS participants will serve as the replicate study participants. A total of 200 repeated measures will be done for remainder of the recruitment phase of the JHS. The proposed sample was arrived at by rough calculations using studies by Nathan et. al. *(Chest 1979 Oct; 76 (4):384-8)*, Enright et. al. *(Am Rev Respir Dis 1991 Jun; 143(6):1215-23)* and Kunzli et. al. *(Eur Respir J 1995 Mar; 8 (3):371-6)*. Given that there are four technicians who perform PFT, the 200 repeated measures will translate into 80 repeats by the same technicians (a pair of 20 per technician) and 120 repeats by a different technician. Though each technician will perform 20 repeats as the second technician, the number 120 is equivalent to the product of 20 and 6, where six (6) is possible ways of combining 4 persons taking two at a time.

Selection & Assignment Study units – The Coordinating Center working in collaboration with the Examination Center and the PFT Reading Center will design the randomization and assignment schemes to carry out this study. Assuming that these 200 participants will be recruited for this replicate study over

a two-year period from the start of the study then it will require about 2 participants per week to complete this study.

3.1.6 Study Plan – Carotid Ultrasound:

Task (Activities) - The replicate study in this case will utilize two approaches. One approach hence referred to as Approach I, will involve repeating scans for a random subset of JHS participants. The other approach hence referred to as Approach II, will involve blindly rereading single scans by the same reader or by a different reader.

Approach I*:* JHS participants will be randomly pre-selected prior to clinic visit to have a second imaging done by either the same technician or by a different technician. In the case of the second imaging done by a different technician, the second technician will also be randomly selected to perform the task.

Approach II**:** A random selection of single scans will be blindly reread by the same reader or by a different reader.

Target Sample –

Approach I**:** A total of 250 JHS participants will be utilized in this replicate study. This translates to a little over 25 participants per technician in both cases where the pair measures are done by the same technician and then where the repeated measure is by a different technician. This is because there are four technicians trained to perform carotid ultrasound. There are four ways of obtaining repeated measures by the same technician (25 participants per technician) and six ways of obtaining repeated measures by a different technician (25 participants per technician).

Approach II**:** The sample units in this case are the single images of JHS participants. A total of 326 images (5% of total JHS sample) will be randomly selected for this aspect of the study. The same reader will blindly reread 50% (163) of the total sample other 50% by a different reader.

Selection & Assignment Study units –

Approach I*:* The Coordinating Center is working in collaboration with the Examination Center and the Ultrasound Reading Center will designed the randomization and assignment schemes to carry out this study. Assuming that approximately 200 participants will be recruited for this replicate study over a two-year period from the start of the study then it will require about 2 participants per week to complete this study.

Approach II*:* The Coordinating Center working in conjunction with the Examination Center and the Ultrasound Reading Center will design a randomization and blinding scheme to carry out this aspect of the replicate study.

3.1.7 Schematic of Repeated Measures per Week:

This schematic is based on: a) a five-day clinic week, b) repeating measures on first six participants per each clinic day, and c) replicating on a total of 15 measures. The first six participants will be used for two reasons. The reasons are: 1) It is being assumed that the arrival of the participants at the clinic is random; and 2) Though the number of participants per day will fluctuate, the minimum per day will be six. The measures are numbered in Table1 below. This schematic will be generated by the Coordinating Center for the Clinic Manager every two months. This will help maintain the random assignment of repeated procedure to participants. The repeats of procedures 1 – 6 contributed by an individual to makeup a phantom are collected on the same clinic visit of a participant.

Table 2: Assignment of Repeated Procedure to Participants per Week

Day of Clinic Visit	Combination of Repeated Measure & Participant (M, P)					
1	(6, 4)	(12,2)	(4, 1)	(2,6)	(13,5)	(7,3)
2	(3,3)	(1,2)	(9,1)	(11,5)	(10,4)	(8,6)
3	(5,5)	(14,3)	(15,6)	(6,2)	(4,4)	(3,1)
4	(7,2)	(12,3)	(9,6)	(11,4)	(8,5)	(10,1)
5	(13,1)	(14,2)	(15,6)	(1,5)	(5,4)	(2,3)

Note*: M=denotes the number of the repeated measure; P=denotes the number of a participant in the order in which he/she arrives in the clinic(1 = 1st participant and 6 = 6th participant).*

Table 3: Numbering and Description of Repeated Clinic Procedures

Procedure Number	Description
1	Venipuncture: Tubes 1 & 2
2	Venipuncture: Tubes 3 & 4
3	Venipuncture: Tubes 5 & 6
4	Venipuncture: Tube 11
5	Venipuncture: Tube 12
6	Urine
7	Height
8	Weight
9	Waist Girth
10	Neck Girth
11	Heart Rate & 1st & 2nd Sitting BP
12	Max Inflation, 1st & 2nd Ankle-Brachial BP
13	Echo
14	Pulmonary Function Test
15	Ultrasound

4.0 ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

The methods to monitor the quality of the JHS data collection process include analyses of the study data itself. This section provides a summary and discussion of the analysis of the study data for quality control purposes. To monitor the data entry process, most variables in the JHS database are analyzed periodically, by the Coordinating Center, in terms of:

1) Status of the variables for each participant record (no problem, skipped due to skip rule, problem with the entry).
2) Frequencies for categorical variables, or means, standard deviations and selected percentiles for continuous variables.
3) Frequency of digit preference analysis.
4) Quality control charts or plots.
5) Univariate and comparative analysis of current data and previous lab data on a monthly basis.
6) Monitoring of lab data on each transfer to identify changes in previous data due to re-analysis of specimen by lab.

The first item, especially, allows a view of the prevalence of data entry problems.

Summary statistics by technician (monthly) or by period of observation (quarterly) are generally not sufficient for quality control purposes, due to the large amount of explained variation in a small amount of data. For example, the means of weight measurements made by two technicians may differ simply because of age or sex differences between the two groups examined. In order to adjust for such known sources of variation, the Coordinating Center periodically examines selected items of study data in terms of age- and sex-adjusted means by technicians. In addition to looking at differences among technicians within the Examination Center in a given reporting period, the Coordinating Center also looks at trends in adjusted means and in variability after adjustment, over time. Relatively sudden shifts in the mean for a given technician or field center or increases in measurement variability after adjustment may indicate that changes in measurement technique have occurred which should be examined. Similar analyses of trends in the study data's summary statistics monitor laboratory data for signs of measurement drift or reduced measurement precision. Certain measurements, which involve a degree of subjective judgment by technicians, such as blood pressure or anthropometry data, are commonly subject to digit preference. The Coordinating Center periodically analyzes such data for digit preference, by technician. Technicians will be provided feedback on their performance of quality data collection. A sample report is provided in Appendix III.

Some data sent to central reading centers (e.g. ECG, pulmonary function tests, ultrasound) are assigned a quality grade by the respective reading centers. The Coordinating Center prepares periodic summaries of recorded quality grade, broken down by technicians or Reading Center to monitor performance.

Certain items of data (e.g. fasting time before blood drawing) give information on protocol adherence and the validity of data obtained from each participant. The Coordinating Center periodically analyzes these data items technicians. The Coordinating Center monitors on a monthly basis the frequency with which each technician performs specific procedures in participant exams, comparing this frequency with the minimum number of exam required to maintain proficiency.

The IDs of technicians for the various procedures will be crossed checked with the procedures that the technicians have been certified in. Violation of protocol will be communicated to the PI or Co-PI of the Examination Center. This check is to ensure that only certified technicians for specific procedures are involved in the data collection for those procedures.

5.0 QUALITY CONTROL REPORTS FOR THE COHORT COMPONENT

A large number of reports are generated by quality control work. In order to spread out the workload and the distribution of the reports, a schedule for the Cohort Component reports has been developed.

Frequency of reports varies from bimonthly to semi-annually, although there are summary reports which are more of a historical nature, covering longer periods. For a report to be of use in correcting problems in data gathering, it must appear more frequently and be prepared as soon as possible after the end of the period covered. The frequency of reports is determined by balancing the study's need for prompt and frequent monitoring with the available resources to generate such reports and the need to accumulate enough data to have an adequate sample size. For example, analysis of adjusted means by technician and of repeat measures in anthropometry is not feasible on a monthly basis, but can usefully be done semi-annually or quarterly. Digit preference analyses, however, are feasible on a quarterly basis for blood pressure.

The standard QC reports generated for the categories within the Cohort Component are outlined below.

1) Certification
    a. Number of technicians certified by area
    b. Number of studies performed in past month, by area, and technician
    c. As in (b.), for the past two months. This report documents, which technicians are not performing enough studies to maintain certification.

    Note: *In addition to the bimonthly reports, semi-annual reports are also produced to account for revisions generated by the bimonthly reports.*

2) Anthropometry
    a. Digit preference (quarterly)
    b. Repeated measures (semi-annually)
    c. Adjusted means by technician (quarterly)

3) Sitting Blood Pressure
    a. Digit preference (quarterly)
    b. Adjusted means by technician (quarterly)
    c. Analysis of serial measures (three repeat measurements within a sitting) (every four months)
    d. Cuff size checks (every four months)

4) Laboratory (lipids, hemostasis, clinical chemistries, hematology)
    a. Repeated measures (monthly)
    b. Condition of sample on arrival (monthly)
    c. Analysis of QC samples from frozen storage (semi-annually)
    d. Internal QC results (quarterly)
    e. External QC results (frequency varies)

5) Pulmonary Function
   a. Acceptability and reproducibility by technician (quarterly)
   b. Adjusted means by technician (semiannually)
   c. Results of test pool submissions (semi-annually)
   d. Comparison of remeasured spirograms by Pulmonary Function Reading Center (monthly)

6) ECG
   a. Mean quality grade by technician (quarterly)
   b. Results on test pool submitted to ECG center (quarterly)
   c. Results on test pool of 12-lead ECGs submitted to ECG Reading Center (quarterly)
   d. Summary of adjudication of Minneapolis/Halifax disagreements (semi-annually)

7) Ultrasound
   a. Frequency of nonvisualized boundaries, by technician and site/angle (quarterly)
   b. Sonographer repeat studies (quarterly)
   c. Reader repeat studies (quarterly)
   d. Adjusted means by sonographer (semi-annually)

8) ECHO
   a. Frequency of nonvisualized boundaries, by technician and site/angle (quarterly)
   b. Sonographer repeat studies (quarterly)
   c. Reader repeat studies (quarterly)
   d. Adjusted means by sonographer (semi-annually)

9) Ambulatory Blood Pressure Monitoring
   a. Frequency of error codes (quarterly)
   b. Adjusted means by technician over time (quarterly)
   c. Failure rate by technician over time (quarterly)

10) Venipuncture
   Distribution of number of stick attempts, means and distribution of filling and processing time (every two months)

Technicians who consistently (2 consecutive analyses) have clinical and/or statistical significant difference in the repeated measures will receive written communication of the significant differences in the repeated measures of the specific measurements. If these differences persist for a given technician then the SSQC will recommend that the technician be subject to retraining of that (those) procedures.

6.0 SPECIAL STATISTICAL ANALYSES IN QUALITY CONTROL REPORTS

6.1 Monitoring for Digit Preference:

Monitoring for digit preference for blood pressure and for anthropometry is done by the Coordinating Center (CC) every two months. Summary reports are sent to the SSQC, and reports of individual technicians are sent to the Examination Center (EC). The actual technician specific frequencies of final digits recorded are not revealed to the Examination Center, to prevent technicians from over compensation to avoid digits that they had preferred in previous reports. For blood pressure only final digits 0, 2, 4, 6, 8 are possible, while for anthropometry 0, 1, 2, 3, 4, 5, 6, 7, 8, 9 are all possible. A Pearson chi-square goodness-of-fit test is done to test the null hypothesis that all possible final digits are observed with frequency N/k (where k is 5 and 10 for blood pressure and anthropometry, respectively). The statistic is calculated as:

$$\chi^2 = \frac{\sum_{i=1}^{k} (O_i - N/k)^2}{N/k}$$

where O_i is the observed frequency of the ith possible digit and $N=\sum O_i$ (i=1,2, .., k).

For large N, this statistic is distributed approximately as a chi-square distribution with k-1 degree of freedom. Also, $\chi^2 = 0$ if the observed numbers for each possible digit is equal to N/k. For validity of this test $N \geq 25$ for blood pressure and $N \geq 50$ for anthropometry are required. A significance level of 0.05 ($p < 0.05$) is used to determine if the divergence from a uniform distribution of digits is statistically significant. However, with large enough N, even small deviations from uniformity are declared statistically significant. Thus, JHS has adopted the use of "digit preference score (DPS)" used in the Atherosclerosis Risk in Communities (ARIC) Study. This score, DPS, is expressed as follows:

$$DPS = 100\sqrt{\chi^2/(k-1)N}$$

This score can be shown to have values between 0 and 100 (It is 0 when all observed digit frequencies (O_i; i=1,2, .., k)are N/k and is 100 when all observed frequencies are all in one cell). Using the cut off point used by ARIC; a $DPS \geq 20$ is the threshold for marked digit preferences. A technician is judged to show "strong evidence of digit preference" if all of the following are true: (1) $N \geq$ minimum N required (25 for blood pressure and 50 for anthropometry); (2) the p-value for χ^2 statistic is < 0.05; and (3) the digit preference score (DPS) is greater than or equal to 20. The Table below illustrates a technician specific report as is pertains to digit preference.

Clinic Visit – Blood Pressure (BP) Digit Preference on Three BP Readings.
Data Received at CC for << Date – Month & Year>>

Technician Code =

Measurement	N	Most Freq.	2nd	3rd	4th	Least Freq.	Probability*	Digit Preference Score (DPS)
Systolic BP								
Diastolic BP								
Random Zero								

* Probability of at least this much variation if no digit preference.
If digit preference persists over a number of months, it is requested that the technician be re-trained. Digit preference monitoring is also used in determination of re-certification.

Replicate Data Analysis:

Paired T-Test : will be used to determine whether or not the difference between the repeated measures are significantly different from zero. If there is no significant difference (i.e. $p > 0.05$), it implies the net difference between the repeated measures is not statistically different.

Reliability Coefficient (R): This is one of the quantities of interest in considering data quality. It is expressed as:
$R = \sigma_b^2/(\sigma_b^2 + \sigma_e^2)$ which is one minus the proportion of total variance due to lab variation. It can also be shown that R is the correlation coefficient between two laboratory measurements made on the same (split) sample. This coefficient, R may be estimated in two ways: (1) from the replicate data alone, using the technique of one-factor random effects ANOVA, divide the total variance in the replicate data into estimates of σ_b^2 and σ_e^2; (2) by combining the information from the replicates with the information from the total JHS study data set. From the sample variance of the study data, S_T^2, we may obtain good estimate σ_T^2. Then, σ_b^2 is estimated by $S_T^2 - \sigma_e^2$, so that the estimate of R is given by

$$R = 1 - (\sigma_e^2/S_T^2).$$

R is useful for overall assessment of the reliability of the measurement method. For routine monitoring of the data collection process, the standard deviation σ_e is most closely watched. In monitoring laboratory data, σ_e for each assay is compared with the target standard deviation (S.D.), which the laboratory has set based on analyses of internal quality control pools. Blind replicate estimates of the laboratory S.D., which are more than twice the target S.D. are considered cause for concern.

Coefficient of Variation (CV): is another index of reliability often used in epidemiologic studies. It is standard deviation (S.D.) expressed as a percentage of the mean value of two sets of paired observations. In an analysis of reliability data, it is calculated for each pair of observations and then averaged over all pairs of original and repeated measures. The lower the CV, the less variation there is between the replicate measurements. Obviously, if there are no differences whatsoever between paired values (perfect agreement), the CV value would be zero.

Outliers: are extreme observations in a set of data points. Using the maximum normal residual (MNR), sometimes called the extreme studentized deviate (ESD) we will detect outliers. These values will be double checked with the EC to ensure that they are not due to data entry error or that they are not clinically plausible, thus they are true outliers.
Descriptive Statistics: these statistics will be generated to examine the distribution of the various means. These statistics will give us a clear sense of our data in very simplistic terms.

Control Charts: These quality control charts will be used to assess the quality of the data. Using the SAS/QC procedures a number of these charts or plots will be constructed.

7.0 QC ANALYSES ON THE VARIOUS CLINIC PROCEDURES/MEASURES

7.1 VENIPUNCTURE AND EQUIPMENT RECORDS

- For equipment, daily records should be kept on all refrigerators and freezers.
- The temperature of the refrigerated centrifuge must be recorded daily.
- The speed of the centrifuge must be checked and recorded annually by a tachometer.
- The local blood processing certifier will fill out the Quality Control Checklist (Appendix 6) monthly, certifying that daily checks have been performed properly and describe any problems in this area.
- Daily checks of freezer alarm.
- Daily checks of the back-up generator to the freezer.
- Daily logs of lab equipment will be sent to the CC for review and analysis.
- The monthly Quality Control Checklists should be kept in a permanent file in the Examination Center.

Notes

- Every 6 months a SAS transport file will be generated by Tufts, which will include daily totals of the recalls and FFQ. This will be sent to JHS staff electronically.

7.2 FAMILY STUDY

Quality Assurance

Pedigrees

Family structure programs (including S.A.G.E®, Progeny2000®, Pedsys®, etc.) will be used for error checking on the pedigree data structure. Several structural errors may be detected including married persons with the same sex code, an individual who is his or her own ancestor, more than one person having the same ID. These programs may also identify certain types of consanguineous matings and loops in the pedigree.

Samples

See Manual 9, Sample Collection and Processing for quality assurance in handling DNA and blood samples for immortalized cell lines.

Genotypes

As genotype information becomes available, marker-typing incompatibilities will be checked. Given an individual's genotype, inconsistencies with parents and offspring data will be verified. For example, we will consider the following inconsistencies:

a. Parent and child alleles are incompatible.
b. There more than 4 alleles in a sibship (brothers and sisters).
c. A sibship has more than 3 alleles in the presence of a homozygous child.
d. Males homozygous for an X-linked allele.

Mendelian consistency will be verified for all pedigrees. It may be necessary to set the genotype of some individuals to missing to save a family.

7.3 SITTING BLOOD PRESSURE

Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed at the Coordinating Center and applied at the Examination Center. These measures include:

1. Recruitment of the most qualified personnel
2. Standardized training and certification
3. Retraining and re-certification
4. Quarterly observation of data collection by supervisors, using the checklist given in Appendix 3. One checklist is used for each technician and sent to the Coordinating Center each quarter.
5. Frequent staff meetings to provide feedback
6. Editing of data, both manual and by computer
7. A quality assurance program administered by the Coordinating Center
8. Quarterly simultaneous Y Tube observation of each technician by the clinic manager
9. Equipment maintenance program

Technician Training and Quality Control

Blood pressure technicians are trained by the clinic coordinator or their designee prior to participant recruitment. New technicians hired after the start of the study are trained locally by the Study Coordinator or a designated "Blood Pressure Supervisor". Recertification occurs every six months. Prior to certification, each technician is required to have a clinical hearing test.

The Coordinating Center directs a blood pressure quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure data, comparing means for each technician with the values for all technicians. These statistics are adjusted for weight, age and sex of the participants. Digit preference is also monitored for each technician.

Equipment Maintenance

The Examination Center is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the blood pressure supervisor and all staff are instructed to report any real or suspected equipment problems to that person promptly.

All checks, inspections, cleanings and problems indicated are documented and recorded by date in a permanent log. Problems and solutions are also recorded. A copy of this log is given in Appendix 4. The

Coordinating Center will obtain from the Examination Center a copy of this log for its file and review. The Coordinating Center liaison to the Examination Center will request for this log monthly.

Random Zero and Standard Sphygmomanometers

The Random Zero manometer is inspected once a week and the standard manometer once a month. These inspections include a check of:

1. the zero level of the standard manometer
2. mercury leakage
3. manometer column for dirt or mercury oxide deposit
4. condition of all tubing and fittings.

The equipment is cleaned if inspection indicates it is needed, or at least once a year. Specific instructions for the random zero device are provided in Appendix 1, and for the standard manometer in Appendix 2. In addition, every two months the accuracy of the random zero instrument is checked using a standard manometer and an Y connection, as described in Appendix 4.

7.4 ANKLE/BRACHIAL BLOOD PRESSURES

Ankle/Brachial
Quality Assurance - Training Requirements

Staff performing the ankle-arm index measurements should be research technicians or clinicians previously trained in taking research blood pressure measurements. In addition, training should include:

- Read and study manual
- Attend Jackson Heart Study training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Compare measurements with those made by experienced colleagues (Goal: obtain measurements within ± 2 mm Hg of that observed by a trainer)
- Discuss problems and questions with EC/CC liaison who in turn will bring the issues to the SSQC for resolution.

Certification Requirements

- Complete training requirements
- Recite exclusion criteria
- Conduct exam on two volunteers while being observed by Clinic Manager listening with Doppler

7.5 AMBULATORY BLOOD PRESSURE MONITORING (ABPM)

ABPM Quality Control Criteria

The Medicom research software automatically evaluates the quality control criteria. One of the following messages will be displayed on the computer screen to indicate the results of a monitoring:

QUALITY CONTROL = PASSED or QUALITY CONTROL = FAILED

The software will automatically place a "QC" code (**1** = PASS or **3** = FAIL) on the first page of the ABPM report to indicate the quality control results.

The following are the minimum quality control criteria:

- There must be a minimum of **24-hours** of data following the "Beginning of Test" time
- Each hour must have a minimum of **1 valid reading**
- There must be a minimum of **54 valid readings** (75% of the 72 programmed readings)

If a participant monitoring FAILED to meet the minimum quality control criteria, please contact Medifacts to discuss criteria for failure prior to the participant's departure from the Exam Center. There may be allowance for acceptance of this monitoring or the participant may be asked to repeat the ABPM procedure.

Repeat ABPM : After discussion with Medifacts, a monitoring failing to meet acceptable quality control criteria may be repeated. All repeat monitoring must be scheduled to occur within 1 month of the failed attempt.

Night Shift Participants: Participants who work third shift (i.e. sleep during the day and work over night) can participate in the ABPM.

Participant Documentation :Each participant will be supplied with a **Participant Instruction Handout**. An activity diary card will not be used during this study.

Participant Report: Two hard copies of the participant's ABPM report will be sent to the clinical center on a weekly basis. A copy of the ABPM report should be kept in the participants' source documents.

Monthly Activity Report: An ABPM activity report will be sent to the clinical center at the end of each month. The report should be reviewed carefully and any discrepancies should be reported to Medifacts. These updates can be communicated via phone, fax or e-mail.

Quality Control Grey Areas: The minimum quality control criteria for the Jackson Heart Study are as follows:

1. The earliest "Beginning of Test" time = **09:00**
2. The latest "Beginning of Test" time = **15:00**
3. There must be a minimum duration of **24 hours** of data from the "Beginning of Test" time
4. Each hour must have a minimum of **1 valid reading.**
5. There must be a minimum of **54 valid readings** (75% of the 72 programmed readings).

Below is a list of each of the minimum quality control criteria. Following each criterion is a possible reason for failure and a suggested action.

Table 4: Grey Area Decision Table

#	Quality Control	Reason for Failure	Decision
1	The earliest "Beginning of Test" time: 09:00.	Beginning of Test time 08:30-08:59	Over-Ride
		Beginning of Test time 08:29 or earlier	Failure, if at all possible repeat ABPM
2	The latest "Beginning of Test" time: 15:00.	Beginning of Test time 15:01-15:30	Over-Ride
		Beginning of Test time later than 15:31	Failure, if at all possible repeat ABPM

#	Quality Control	Reason for Failure	Decision
3	**There must be a minimum duration of 24 hours of data from the "Beginning of Test" time.**	Total time 23:00 - 23:59	Override *
		Total time less than 23:00	Failure, if at all possible repeat ABPM
4	Each hour must have a minimum of 1 valid readings.	There is 1 hour with less than 1 valid reading.	Over-Ride
		There are consecutive hours with less than1 valid reading.	Failure, if at all possible repeat ABPM
5	There must be a minimum of 54 valid readings (75% of the 72 programmed readings).	**There is total of 50 to 53 valid readings (70% of the 72-programmed readings.**	Over-Ride
		There is a total of less than 50 valid readings (less than 70% of the 72 programmed readings.	Failure, if at all possible repeat ABPM

* Note: ONLY if there is a minimum of one valid reading in the last hour. If the last hour is invalid (has no valid readings) and the total time is 23:00 -23:59, then the ABPM should remain a failure and if at all possible repeat ABPM.

7.6 ELECTROCARDIOGRAPHY

Quality Control

The 12-lead ECG

Technician:

1. All ECG technicians must be certified. See the following section on Training and Certification, and Appendix 10 for Certification forms.
2. Study guidelines on "acceptable" noise levels are given earlier in this protocol under Self Evaluation of Technical Performance.
3. Each technician must take an average of 3 ECGs per week over a two-month period to remain familiar with procedures and equipment and to remain certified.
4. Each technician is observed quarterly by the most senior certified technician while taking a participant's ECG. The observer checks whether or not each procedure is performed (Appendix 11) and makes comments on the sheet if necessary. After the ECG is taken, the observer discusses the Procedure Review with the technician, and sends it to the JHS.

JHS Clinic Center

1. Each ECG is checked for quality of data in Minnesota.
2. The technician number and Performance Grade Level (Appendix 6) of each ECG is included in the data file that is sent to the ECGRC each month.
3. The ECGRC reports these findings to the JHS.
4. Each MAC PC is calibrated quarterly. Procedures are in Appendix 12.

ECG Computer Coding at the ECG Reading Center:

Blind rereading of baseline ECGs is performed in two ways:

1. The abnormal quality control ECGs that are retransmitted are returned to the ECG Reading Center with the other abnormals. The ECG Reading Center makes no effort to distinguish these returned ECGs from the rest of a normal shipment. They are coded and reported in the usual manner. Thus, the ECG Reading Center continually rereads the quality control ECGs determined to be abnormal. (The quality control ECGs determined to be normal are only sent to the ECG Reading Center if they are chosen to be part of the 10% sample of normals that is included with the abnormals.)

2. A 25% sample of computer defined abnormal are visually over-read. A 10% sample of normals is also visually over-read. The over-reading is done using the same “average” beat used by the computer program.

7.7 ECHOCARDIOGRAPHY

Quality Assessment

General:

The utility of echocardiographic measures of cardiac anatomy and function has been demonstrated in clinical and population studies. Cardiac abnormalities assessed by these techniques (e.g., left ventricular hypertrophy) have been associated with an increased incidence of cardiovascular morbidity and mortality. Given the greater sensitivity and specificity of echocardiographic measure in comparison to other indirect measures of cardiac abnormalities, the echocardiogram may serve as a surrogate measure of preclinical manifestations of cardiovascular disease and as a prognostic indicator for future clinical events (i.e., hypertension, myocardial infarction, and/or stroke).

Since this is a large scale population study of African-Americans from which a very valuable data set will be generated, quality control is of particular importance. Previous population studies (ARIC, Framingham Heart Study, CARDIA, and CHS) have indicated that considerable training and experience are required to assure optimal echocardiographic data acquisition of sufficient quality. The goals of this strict echocardiography quality control program are to (1) provide quantitative documentation of the reproducibility of the scanning and reading procedures, and (2) assure the comparability of the JHS echo scanning and reading procedures with ARIC and other important echocardiography data sets.

Essential Features of the Quality Control Program:

1. To assure adherence to study protocol, supervision of the performance of echocardiographic procedures utilized by technicians will be done by the Echo Reading Center cardiologist staff, each highly experienced in echo methodology and research.
2. Regular meetings among technicians and reading center physicians will be conducted. At these meetings, the staff will critically review studies to identify opportunities for improvement in data quality and security, and in efficiency and details of protocol. The technicians will better recognize the image quality and techniques necessary to allow the study readers to obtain accurate, reproducible quantitative information. At the same time, the study cardiologists can provide ongoing feedback to improve the technicians' skills, their understanding of ultrasound principles, and their recognition of echocardiographic abnormalities.
3. To identify potential protocol deviations, difficulties, or inefficiencies, consultant experts in the field may periodically visit the Examination Center to assess scanning and reading procedures.
4. Assessment of inter- and intra-technician/reader variability.

Assessment of Intra- and Inter-Reader Variability During the Pilot Phase:

To provide estimates of intra-reader repeatability, after initial reading of the pilot phase testing/certification, 50% of the scans will be reread by the same reader. The remaining 50% will be read by a second reader. Additional repeat readings will be performed throughout the study.

In addition to the above quality control procedures a random sample of 20 echocardiograms performed during the first three months of the study may be sent to consultants for reading.

Assessment of Intra-technician Variability During the Examination Period:

Intra-technician variability will be assessed throughout the examination period by the performance of quality control repeat echocardiograms in a 5% random sample of participants. The Coordinating Center will generate a list of randomly selected JHS IDs for the purpose of QC repeat examinations. After the initial scan on each participant is complete, the technicians will check the QC master list to determine eligibility of the participant for repeat measurements. If the participant's ID matches the QC list, he/she will be asked to volunteer for a repeat echocardiogram.

7.8 ULTRASOUND

Certification of New Sonographers:

When a novice sonographer has successfully met all training requirements, as outlined in Section 9.1, written notification is sent to him/her and to the study coordinator at the field center, informing the novice sonographer of his/her new status as a certified sonographer.

Retention of Certification by Experienced Sonographers:

A sonographer retains certification to scan based upon the demonstrated ability, while following the JHS scanning protocol, to visualize arterial walls in a fashion consistent with that of other certified sonographers participating in the study. Study data will be evaluated by the Ultrasound Reading Center on a regular basis to examine visualization rates and arterial dimensions contributed by each sonographer to assist in the identification of individuals performing differently than their peers. In addition, at least one scan performed by each certified sonographer per month will be reviewed at the Ultrasound Reading Center for compliance with the study protocol. So long as a sonographer maintains visualization and arterial dimensions consistent with the process average of their peers and the average of monthly review scans meet protocol standards, he/she retains certification. If, however, sonographers exhibit difficulty in performing in a fashion consistent with their peers or in passing monthly scan reviews, remedial action will be initiated. If these problems remain unresolved, decertification may become necessary as described in Section 9.2.4. Sonographers who submit no scans suitable for monthly review for two consecutive months will be considered to have lapsed certification. Experienced sonographers may be recertified after submitting 5 scans that pass certification review.

Guest Sonographers

During the course of this Study it is expected that, upon occasion, a sonographer will be unavailable to scan participants without being able to give sufficient prior notice to allow for a reschedule of the participant's visit. If no provisions were made for such an eventuality, participant's would be unduly inconvenienced, or may refuse to return to undergo an ultrasound evaluation. In such a case, in order to prevent a loss of valuable data, the services of a guest sonographer may be used. A guest sonographer is one who is well-versed in the applied principles of carotid ultrasound, and who is familiar with the JHS ultrasound scanning protocol and study equipment. The names and qualifications of guest sonographers are to be registered with the Ultrasound Reading Center, where they will be assigned ID numbers.

Prior to substituting for a certified sonographer for this Study, the guest sonographer is to read the protocol, and review it with the lead sonographer or, in her absence, another JHS certified sonographer. Tapes containing scans recorded by the guest sonographer are to be clearly marked to that effect. Likewise, a notation is to be made on the log sheet.

Upon receipt of these tapes at the Ultrasound Reading Center, these tapes will not be logged in with the tapes produced by certified sonographers. The trainer at Ultrasound Reading Center will first review the tapes. If the scans are found to conform to protocol, they will be logged in and treated from then on in the standard fashion. If, however, the scans are found not to conform to protocol, the scans will not be

logged in and will not be read. The field center coordinator, chief sonographer and guest sonographer will be informed of the areas where the scan did not conform to the protocol.

Due to the additional effort required to process these scans, no guest sonographer may scan for more than five days or fifteen scans within a two month period without first obtaining special permission from the Clinic Operation Committee of this Study and the Carotid Ultrasound Center Director. Should the Examination Center require additional sonographer support for an extended period, guest sonographers must undergo additional training as specified by the Ultrasound Reading Center in order to become certified for this study. The guest sonographer must submit scans for review for certification and become certified when scanning longer than a five days or fifteen scans within a two month period. At least five scans must pass review before certification can be attained.

The EC/CC liaison will check with the Examination Center to gather information on any scanning or reading problems. Such problems will be logged at the Coordination Center and the issues referred to the SSQC for deliberations on the matter.

Loss of Certification

Though none of the sonographers with the JHS has lost his/her certification, when a sonographer's boundary visualization rate or measured arterial dimensions depart substantially from those of other sonagraphers or if his/her average monthly scans reviewed do not meet protocol standards, both the sonographer and the Clinic Manager will be notified of the specific nature and extent of the problem and a plan for remedial action will be developed in conjunction with the Ultrasound Reading Center. Remedial action may require refresher training at the Ultrasound Reading Center or Examination Center.

Scanning Process Control

Timely feedback is critical to the success of this procedure. Therefore, on a routine basis, based on frequency of scanning and sonographer consistency, sonographers will be given detailed reports of their performance, and be notified of the extent to which they conform to the quality and quantity of data gathering exhibited by the Study sonographers as a group. Below are indicated the steps to be followed based on each sonographer's conformance to these standards.

Conforming

- The sonographer and the Clinic Manager will receive written notification of her scanning performance.
- The sonographer will continue to scan.
- The Ultrasound Reading Center will continue to monitor levels of visualization.

Non-conforming - slight

- The sonographer and the Clinic Manager will receive written notification of her scanning performance.
- The sonographer will review the scanning protocol.
- Another sonographer will observe the sonographer perform that part of the scan which was found not to conform to standards and make recommendations for improvement.
- The sonographer will discuss with the reviewer/trainer at the Ultrasound Reading Center ways to improve protocol adherence.
- The sonographer will report back to the Ultrasound Reading Center on the steps taken to effect the improvement.
- The sonographer will continue to scan.
- The Ultrasound Reading Center will continue to monitor levels of visualization.

Non-conforming - moderate

- The sonographer and the Clinic Manager will receive written notification of the sonographer's scanning performance.
- The sonographer will review the scanning protocol.
- The sonographer will review training materials on the principles of physics and anatomy.
- The Ultrasound Reading Center trainer/reviewer will identify patterns which might reveal the reason for failing to conform to the standard, document areas in need of improvement, and communicate her findings to the sonographer.
- Another sonographer will observe the sonographer perform that part of the scan which was found not to conform to standards and make recommendations for improvements.
- The sonographer will practice that part of the scan on volunteers.
- The sonographer will report back to Ultrasound Reading Center on steps taken to effect improvement.
- The sonographer will continue to scan.
- The Ultrasound Reading Center will continue to monitor levels of visualization.

Non-conforming - severe

- The sonographer and the Clinic Manager will receive written notification of the sonographer's scanning performance.
- The sonographer will stop scanning cohort participants immediately.
- The sonographer will review training materials on the principles of physics and anatomy.
- The sonographer will review the scan protocol.
- The Ultrasound Reading Center trainer/reviewer will identify patterns which might reveal the reason for failing to conform to the standard, document areas in need of improvement, and communicate her findings to the sonographer and the study coordinator.
- The Ultrasound Reading Center and Field Center staff will jointly develop a remedial plan, including detailed steps required for recertification.
- When the Ultrasound Reading Center determines that improvement has been demonstrated, with visualization at or above the study average for all sites, the sonographer will be recertified and may resume scanning study participants.
- The Ultrasound Reading Center will continue to monitor levels of visualization.

Monitoring

Sonographer performance is monitored through the Examination Center and the Ultrasound Reading Center.

Monitoring at Exam Center

The B-mode images are evaluated for overall image quality, the presence and clarity of the arterial wall boundaries, and the presence of anatomical landmarks and a cursor indicating the location of an anatomical landmark and the vessel lumen. Copies of all reviews are sent to the Ultrasound Reading Center on a monthly basis and a review log should be maintained at the Examination Center. The Examination Center is encouraged to hold monthly sonographer meetings where equipment issues, protocol interpretation, and review results can be discussed.

Monitoring at the Ultrasound Reading Center

Sonographer performance is monitored at the Ultrasound Reading Center using a number of quality assurance procedures. The quality assurance procedures include but are not limited to: (1) comparing results of repeat studies; (2) periodic reports containing statistics of boundary visualization by individual sonographer and study wide; (3) visual review of randomly selected participant scans; (4) on-site monitoring of sonographer performance by designated Ultrasound Reading Center personnel. Reports are generated and distributed by the Ultrasound Reading Center.

In addition, the Ultrasound Reading Center can review the same participant studies reviewed by sonographers at the field center. The sonographer evaluation form is completed at the Ultrasound Reading Center, and the results are compared to the sonographer's form. Any significant differences between evaluations, or any significant problems are discussed with affected sonographers to resolve the differences. Results of these sonographer evaluations are used to help maintain high standards for participant studies and are part of an ongoing sonographer recertification process.

The Ultrasound Reading Center readers read the ultrasound images from all the data collection procedures and the quality assurance images. Image interpretation results from study images and quality assurance images from the same site and angle are compared for use in sonographer quality assurance procedures. The purpose of this evaluation procedure is to determine the consistency and reproducibility of scanning and of interpreting ultrasound images. The results of these evaluations are reported periodically to the JHS Coordinating Center and the field centers.

The B-Mode Study Scan Evaluation Form

The current version of the B-mode study scan evaluation form is on file at the Ultrasound Reading Center in Winston-Salem, NC. This form provides a forum for a detailed accounting of the conformance to scanning protocol as described in this document.

7.9 PULMONARY FUNCTION

TECHNICIAN CERTIFICATION:

The certification examination includes 50 multiple choice questions based on this Manual of Procedures, and a practical demonstration of skills including leak and calibration checks, cleaning, and testing of a naive subject (50 points). A passing score of at least 75 points is necessary for certification. Only certified technicians will perform pulmonary function testing in this study.

Certification of new technicians after the initial central training session may be performed by a centrally trained, certified Pulmonary Function technician. The written exam will be administered locally, and the first 10 Pulmonary Function tests performed will be observed by a certified Pulmonary Function technician and then examined by the Pulmonary Function Reading Center and found to be satisfactory before the new technician is certified. The results of the first 50 spirometry test sessions performed by each technician will be closely examined at the Pulmonary Function Reading Center. Copies of sub optimal quality test sessions with comments for improvements will be mailed to the technician the same day as they are evaluated.

A site visit to the clinical center may be made early during the exam year. Complete calibration, leak, and complete Pulmonary Function testing of at least three participants by each Pulmonary Function certified technician will be observed. Copies of sub optimal quality test sessions will be reviewed. More efficient methods as well as protocol violations will be discussed during the site visits and later in a written report.

<u>Need for Spirometry Quality Control</u>:

Examination of spirograms from the Framingham study revealed that more than 18% were of clearly unacceptable quality (11). Two more recent studies, with over 12,000 adults each, found that 40 - 50% of the spirometry maneuvers were of unacceptable quality (12-14). Manual measurements from spirograms

are tedious and prone to error (15), and deviations in test performance and lack of regular leak checking and calibration can result in loss of study data (16-18).

The Epidemiology Standardization Project (19), the new American Thoracic Society spirometry standards (20), and recent evaluations of commercially available spirometers emphasize the importance of spirometry quality control procedures. Factors that affect spirometry quality (22) include:

1. Participant
2. Maneuvers
3. Technician
4. Equipment
5. Analysis

Feasibility of QC Procedures:

Personal computer systems, such as the S&M Instruments system used by the JHS, have been developed and validated by an unbiased University testing program (21). The software assists the pulmonary technician with quality control of maneuvers, calculates the Pulmonary Function variables, suggests interpretations, formats and prints reports, and compresses graphics data for transmission and archival storage (23). The Lung Health Study (24), Cardiovascular Health Study, Framingham Study, and ARIC studies have used similar systems and procedures since 1987. The computerization of spirometry QC procedures dramatically decreases the overhead time associated with spirometry testing.

Implementation of QC Procedures:

There are five separate levels of quality control implemented for spirometry testing which address the five factors known to influence the results:

1. Daily spirometer leak and calibration checks using a 3.000 liter syringe as the "gold standard" check the **equipment** accuracy.

2. Eight computerized checks of FVC maneuver acceptability and reproducibility check **every maneuver** immediately after it is performed.

3. The Pulmonary Function technician is trained to recognize the patterns of unacceptable maneuvers, **watching the participant** during the performance, and reviewing the colorfully displayed flow-volume curves on the computer monitor.

4. The results of the leak and calibration checks and the FVC maneuvers are stored and sent to the Pulmonary Function Reading Center for review by the Pulmonary Function QC Supervisor. Monthly reports are compiled for each **technician's performance**.

5. Results from all of the above are taken into account during the **analysis** of the data by the Pulmonary Function Reading Center (3, 24). The calibration factors, Pulmonary Function tech's impression of participant and maneuver quality, and the QC supervisor's impression of test session quality are all integrated to obtain the final FEV1 and FVC results reported to the Data Coordinating Center.

6. **Replicate testing – See Replicate Studies for details.**

7. After instrument QC checks, a **biologic control** subject (nonsmoker without asthma) will be tested each Monday morning (the Examination Center Clinic Manager or designate is preferred). The results will be compared with their prior mean values for FVC and FEV1.

QC Analysis And Reporting:

Each week the Examination Center will backup all Pulmonary Function data for participants tested during the previous week and the calibration result files. These backup files will be e-mailed to the Pulmonary Function Reading Center. The e-mail address is ldrjens1@ihc.com. This is Dr. Jensen's email address.

At the Pulmonary Function Reading Center, the result files are read by the Pulmonary Function QC workstation. The Pulmonary Function QC workstation displays the FVC maneuvers from a test session as differently colored flow-volume curves superimposed at the onset of each maneuver.

The field center and the Pulmonary Function technician who performed the testing are hidden from the QC Supervisor to avoid bias. The spirometer temperature is displayed and is highlighted if it falls outside the 17-33 degree C range, since BTPS corrections for volume spirometers become less accurate outside of this "normal" range (27).

After evaluating the flow-volume curves and the array of results, the QC supervisor indicates her choice of the single best maneuver, and enters a test session QC grade from A to F for flow (PEF), FEV1and volume (FVC). A flow grade of A is entered if at least 3 maneuvers demonstrate sharp peak flows and if the best two have very reproducible PEFs. A FEV1 grade of "A" is given when the difference between the two best test is less than 100 ml, and a grade of A is given to FVC (volume score) when the difference between the two best FVCs is less than 100 ml.

After over reading a batch of test sessions, the QC grades are added to a QC database. All sessions with either a volume or flow grade of C or less or with a spirometer temperature outside the normal range are printed, comments are added by the QC Supervisor, and a cover letter is added and mailed to the technician who performed the test. The final, over read Pulmonary Function results are generated and sent by mail to the Coordinating Center at least monthly.

At the end of each month, a report is generated from the QC database, summarizing the performance of each Pulmonary Function technician. For each Pulmonary Function technician, the report includes the number of sessions reviewed and their average QC grades. The report is mailed each month to the Principal Investigators and to all Pulmonary Function technicians.

Weekly Biologic Control:

Perform a normal FVC test. Use the same technician and the same ID number for all tests. It should be 999xxx where xxx is the technician's 3 digit ID code. Perform FVC maneuvers as if testing a participant. Store the results and then review the trends. Ensure that your current FEV1 is within 5% of the mean of your previous values. This data is sent with participant results during monthly data transfers from Pulmonary Function Reading Center to the Coordinating Center. The CC will separate the QC data from the rest of participants' results for QC analysis.

7.10 CENTRAL LABORATORY & SPECIMEN COLLECTION

QUALITY CONTROL

Venipuncture and Equipment Records

In the Examination Center there are two different aspects of quality control. One is the daily or monthly record of the performance of the refrigeration equipment and centrifuge. This is most easily kept as a check sheet with the daily or monthly records, as described below. The other aspect of quality control is the Venipuncture Form that is part of each participant's records. It shows the number of attempts it takes to achieve a successful venipuncture and the code number of the technician who performs the venipuncture. This record provides needed documentation that the blood was drawn in a standardized manner and that the equipment was functioning properly. This quality control documentation is the best evidence that all specimens in the Examination Center are being drawn and processed identically. Differences in the way the samples are collected or processed could potentially create a significant difference in assay results, which could seriously compromise the laboratory test data. It is very important that the quality control records of the procedures and the equipment be properly maintained.

For the equipment, daily records should be kept on all refrigerators and freezers. The temperature of the refrigerated centrifuge must be recorded daily. See Appendix 4 for a sample form. In addition, the actual speed of the centrifuge needs to be checked and recorded annually with a tachometer. A sample Quality Control Checklist is enclosed in this manual (see Appendix 5). The local blood processing certifier will fill out this sheet monthly, certifying that daily checks have been performed properly and describing any problems in this area. The Monthly Quality Control Checklists should be kept in a permanent file in the Examination Center.

Quality Control Duplicate Blood and Urine Samples

As part of the overall quality control program for laboratory analyses, duplicate specimens are sent to the laboratory, with one half of each specimen pair sent under the participant's regular JHS laboratory ID number, and the other half under a Quality Control Phantom Participant (QC) laboratory ID number. The QC laboratory ID numbers are not distinguishable from other laboratory ID numbers so that this forms a blinded external quality control program monitoring measurement variability.

To reduce the burden upon JHS participants, no one person is asked to contribute sufficient extra blood to make a complete set of duplicates for all tests. Instead, extra blood is drawn from five participants and sent out under the same QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results.

All QC samples are stored an extra week at the Examination Center and then sent to the Central Laboratory with a regular shipment.

Ideally the QC samples are drawn on five separate days. For example, on Monday draw Tubes 1 and 2 (chemistry); on Tuesday, draw Tubes 3 and 4 (hypertension and glycated hemoglobin); on Wednesday, draw Tubes 5 and 6 (coagulation); on Thursday, draw Tube 11 (anti-protease); and on Friday draw Tube 12 (hematology). Tubes 7 through 10 are not collected as part of the QC program. The QC urine duplicate can be collected on Thursday or Friday.

Weekly Blood and Urine QC Sample Checklist

The JHS Examination Center venipuncture technicians maintain a weekly checklist posted in their work area of the QC samples to be collected during the week. As each sample is drawn and processing completed, it is checked off. On Friday morning, this checklist is consulted to see if there were any additional samples needed to make up the complete set of QC samples. An example of the checklist is given below:

Figure 1. Weekly Blood QC Sample Checklist

Week of: _____

Day	Tubes	Laboratory	Sample collected?
Monday	1&2	Chemistry	_____
Tuesday	3&4	Hypertension/Gly. Hgb	_____
Wednesday	5&6	Coagulation	_____
Thursday	11	Chemistry	_____
Friday	12	Hematology	_____
Thursday or Friday	Urine	Chemistry	_____

Preparation for Drawing and Processing QC Samples

Blood Drawing Tubes: Each morning the blood drawing technician prepares extra blood collection tubes for the QC samples to be drawn that day. Each tube is labeled with the QC ID number to be used that week. In addition, the technician may wish to mark QC tubes "QC" in a clearly visible fashion, to reduce the chance that these tubes might be mixed up with the regular blood collection tubes during processing. The QC tubes are set in the same rack used to hold the regular blood collection tubes, in a separate row from the other tubes.

Sample Aliquot Tubes: Each morning a separate foam block is prepared for each set of QC blood tubes that the technician plans to draw that day. The foam block contains all the storage vials needed to process the day's quality control samples. The tubes in each block are labeled in advance with the QC ID number being used that week. Care must be taken during processing that the labels on the sample aliquot tubes match the label on the QC blood collection tubes.

On the day that the duplicate urine sample is to be collected, six extra tubes for the urine QC duplicates should be set out and labeled with the urine QC ID number. One participant per week is chosen for use as the urine QC duplicate.

Collecting and Processing QC Blood and Urine

Selecting Participants for QC Blood Draw: Normally, the QC samples are drawn from the first member of each group of participants whose blood is being processed simultaneously. Based upon the size of their veins, the difficulty of drawing the blood, and the apprehension a participant shows about the blood draw, the venipuncture technician may need to forego the drawing of the QC tube from the first, and draw from another participant instead.

Order of QC Tubes in Relation to Regular Blood Collection: The QC tubes may be added at the end of the blood draw without harming the measurements. This procedure is followed to cause the least disruption of the collection of the regular blood samples. If the blood flow falls off at the end of the draw, so that it would be difficult to obtain the extra QC tubes, a different participant is used to get this blood. A NEW NEEDLE STICK SHOULD NOT BE DONE JUST TO GET MORE BLOOD FOR A QC SPECIMEN.

Processing and Freezing QC Blood and Urine: QC blood samples are processed along with the regular blood samples. After processing is completed for each QC blood collection tube, the microvials are put into the -70°C freezer (for a minimum of 30 minutes). After the samples are thoroughly frozen, they are put into a freezer storage bag. The QC samples should be kept separate from the other samples collected during the week so they are not shipped along with them.

The urine QC samples should be placed into the freezer at the same time as their matched participant pair. As with the blood specimens, the urine samples should be kept away from the other urine specimens collected during the week so they are not included with that week's shipment.

Logging the Match between QC and Regular JHS ID's and Reporting These to the Coordinating Center: The QC Phantom Participant's folder is kept in the blood drawing area during the week the phantom ID number is being used to draw QC blood tubes. In the folder is the JHS Quality Control Phantom Participant Form, which is used to keep track of the match between the QC and regular JHS specimens. A sample copy is shown in Appendix 8. At the top of the log sheet is a space for the QC Phantom Participant's laboratory ID number. As participants donate blood to make up a QC set, labels with their ID numbers are added to the line corresponding to the tubes donated. This step must be done immediately after completing drawing blood for that participant, to minimize the chance of recording the wrong ID number. One such form is recorded for each QC ID number used. As soon as the full set of tubes is completed for each phantom participant (or at the end of the week, if any set is incomplete), the QC phantom participants' folder with this form is given to the receptionist (or other person designated by the Study Coordinator). The folder is processed like other participants' folders, except that the QC phantom participant form is sent to the Coordinating Center and the Exam Center keeps a photocopy of this form in the phantom's folder. Neither a Venipuncture Form nor Urine Collection Form is completed for the phantom duplicate.

8.0 TRAINING PROCEDURES

Technician Training and Evaluation:

The technician must study the JHS Specimen Collection and Processing Manual and watch several participant samples being processed. Then the technician may proceed to a mock drawing and mock processing of samples, without performing any actual venipuncture. Mock venipuncture is performed with the Vacutainer system. A piece of latex tubing with a knot in one end leading to a glass of water is used as a target vein. Practice tubes are collected in the correct order, then placed at their proper positions. The sample is processed from start to finish exactly as if real blood were being used. Each technician performs a minimum of two mock draws from beginning to end. Although the mock draws take time, they provide hands-on experience and allow the technician to become comfortable with the procedures before proceeding to live participants.

At this point the technicians are ready to practice on live volunteers. The technicians practice at least once with just one volunteer at a time and again process the blood entirely by themselves from start to finish. If the technicians do not feel comfortable, they can repeat the process with dummy tubes. If enough volunteers are available, it may be beneficial to repeat this several times. Any questions or problems that the technicians have must be solved before the technicians proceed to drawing the JHS participants. Before the technicians draw blood from any JHS participant, they must take and pass the practical and written tests included at the end of this manual. After passing the tests and evaluation of their instructor, they may proceed to drawing blood from JHS participants.

Appendix I: Quality Assurance Data Collection Instruments – Field Observation of Recruiters

Form 1: Recruiter Quality Assurance -- JHS Home Induction Interview Checklist

Recruiter:_____ **Date:**

Key:
- N/A not applicable
- 1 Unsatisfactory (failed to meet standards)
- 2 Below expectations (did not meet some standards
- 3 At expectations (met standards)
- 4 Above expectation (met all standards and in some cases exceeded them)
- 5 Outstanding (distinguished consistently exceeded all standards)

1. On time for interview	N/A	1	2	3	4	5
2. File prepared	N/A	1	2	3	4	5
3. Professional behavior	N/A	1	2	3	4	5
4. Professional attire	N/A	1	2	3	4	5
5. Answers respondent's questions and concerns	N/A	1	2	3	4	5
6. Speaks slowly and distinctly reading the questions at neutral (but expressive) and even pace	N/A	1	2	3	4	5
7. Maintains the focus of the interview but allows participant to express thoughts	N/A	1	2	3	4	5
8. Follows instructions/reads questions as written	N/A	1	2	3	4	5
9. Initiates (where needed) appropriate, non-leading question	N/A	1	2	3	4	5
10. Records/codes answers correctly (follows skip patterns as needed)	N/A	1	2	3	4	5
11. Completes the editing process and reviews forms	N/A	1	2	3	4	5
12. General overall rating	N/A	1	2	3	4	5

Comments:

_____

Corrective action taken:

_____

Supervisor's Signature:

_____

Form 2: Recruiter Quality Assurance -- Phone Calls of Participants

QA Phone Calls ***Week:***

Recruiter	***Participant***	***Phone #***	***Comments***
207			▪ ***On time*** ▪ ***Prepared*** ▪ ***Knowledgeable*** ▪ ***Professional behavior*** ▪ ***Professional attire***
208			▪ ***On time*** ▪ ***Prepared*** ▪ ***Knowledgeable*** ▪ ***Professional behavior*** ▪ ***Professional attire***
209			▪ ***On time*** ▪ ***Prepared*** ▪ ***Knowledgeable*** ▪ ***Professional behavior*** ▪ ***Professional attire***
: ***:*** ***:*** :			▪ ***On time*** ▪ ***Prepared*** ▪ ***Knowledgeable*** ▪ ***Professional behavior*** ▪ ***Professional attire***
255			▪ ***On time*** ▪ ***Prepared*** ▪ ***Knowledgeable*** ▪ ***Professional behavior*** ▪ ***Professional attire***

Note: Recruiter Codes are: 207, 208, 209, 210, 211, 222, 223, 250, 251, 252, 255, ***.

Appendix II **Evaluation Tools to monitor Clinic Operations by CC/EC Liaison.**

Jackson Heart Study Annual Schedule of Staff Certification, Criteria

Technician ID No._____

Study Component	Certification Criteria	Date Completed	Comments
1. Exam Center Study Procedures/Protocol	Observation by Clinic Manager or designee		
2. Technician Practices/Performance	Evaluation by Reading Centers		
3. Medical History (MXH)	1 taped interviews by CC		
4. Respiratory Symptoms(RPA)	1 taped interviews by CC		
5. Stroke (SSF)	1 taped interviews by CC		
6. Reproductive History (RHX)	1 taped interviews by CC		
7. Alcohol & Drug Form(ADR)	1 taped interviews by CC		
8. Discrimination (DIS)	1 taped interviews by CC		
9. Contact Form (CON)	1 taped interviews by CC		

Jackson Heart Study Exam Center Quality Control Weekly Checklist

Study Component	Quality Control Criteria	Date Completed	Comments
1. Anthropometry	Review of Logs		
2. Venipuncture and Specimen Processing	Review Equipment Checklist Review Blood and Urine Sample Checklist		
3. Ambulatory Blood Pressure	Review Inventory of Equipment		
4. Pulmonary	Review of Equipment Performance Checklist Log		
5. Informed Consent Forms	Check for Completion		

Jackson Heart Study Exam Center Quality Control Checklist

Study Component	Quality Control Criteria	Frequency	Date Completed	Comments
1. Anthropometry	Review of Equipment Checklist	Semi-annual		
2. Electrocardiograph (ECG)	Review of ECG Training Supervisor's Log	Semi-annual		
3. Electrocardiograph (ECG)	Check Calibration of MAC PC	Quarterly		

Jackson Heart Study Exam Center Quality Control Monthly Checklist

Study Component	Quality Control Criteria	Date Completed	Comments
1. 24-Hour Urine Collection	Review of Forms		
2. Blood Pressure	Review Log Check Maintenance of Sphygmomanometer Monthly Activity Report		
3. Electrocardiograph (ECG)	Review Log of Data Sent to Reading Centers Review MACPC maintenance		
4. ECHO	Review Random List Generated for Repeat Exams		
5. 5. UltraSound	Review Log Sheets Review Records of Equipment Maintenance		
6. Pulmonary	Review Replicates List		

Appendix III: Evaluation/Certification/Site Visit Checklist

JHS Data Management Certification / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Manager Trainee Name/ID: ☐

Data Manager Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Site Visit ☐

Please check the appropriate box if manager performance is satisfactory for each line item. Note comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Enrolls participant in Clintrial DMS.
2. ☐ Enters results of contact attempts (HER, IRC) into Clintrial data entry system.
3. ☐ Enters final recruitment status (IRC) using the DMS form.
4. ☐ Enters Home Induction Interview using appropriate DMS forms.
5. ☐ Enters participant contact information using the DMS form.
6. ☐ Enters appropriate DMS forms by direct data entry during participant clinic visit.
7. ☐ Enters clinic paper forms using appropriate DMS forms.
8. ☐ Performs timely transmissions to Reading Centers.
9. ☐ Performs weekly transmission to CC.

Comments: _____
_____
_____

Corrective action taken: _____
_____
_____

Supervisor / Site Visitor Signature_____

JHS Delta NIRI Food Frequency Questionnaire Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Staff Name/ID: ☐

Evaluator Name/ID: (DPASS Staff) ☐

Purpose of Evaluation:

Certificati on ☐ Supervisor QC Check ☐ Site Visit ☐

Quality Control Checklist For Review of All JHS Diet Interviews	**Circle Yes or No**		**Problem Resolved (Enter date resolved)**
1. Was participant ID# recorded & correct?	Yes	No	
2. Was interviewer ID# recorded?	Yes	No	
3. Does the day of week identified match the appointment calendar?	Yes	No	
4. Was the date recorded correctly?	Yes	No	
5. Did the interviewer record the time the interview began?	Yes	No	
6. Did the interviewer record the time the interview ended?	Yes	No	
7. Did the interviewer speak clearly?	Yes	No	
8. Was the interviewer respectful to the participant?	Yes	No	
9. Were cue cards used appropriately?	Yes	No	
10. Were estimation tools used appropriately?	Yes	No	
11. Was the interviewer enthusiastic?	Yes	No	
12. Were all questions answered?	Yes	No	
13. Was the QC tape routed per protocol?	Yes	No	
JHS Diet Data Review			
15. Enter the date verified			
16. Enter the QC Reviewer's ID number.			
17. Comments relating to data:			

Comments: _____

_____

_____

Corrective action taken: _____

_____

_____

Evaluator Signature _____

JHS Interviewer-Administered Questionnaire Supervisor / Site *Visit Checklist*

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Interviewer Name/ID: ☐

CC Clinic Liaison Name/ID: ☐

Interview/form reviewed (Taped Interviews of Two Questionnaires):

Discrimination ☐ Medications ☐ Medical History ☐

Reproductive History ☐ Respiratory Symptoms ☐ Stroke Symptoms ☐

Alcohol ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page.

Key: N/A – Not applicable
1 – Unsatisfactory (failed to meet standards)
2 – Satisfactory (met standards)
3 – Excellent (distinguished consistently exceeded all standards)

Informed participants of procedures?	**N/A**	**1**	**2**	**3**
Spoke clearly and audibly?	**N/A**	**1**	**2**	**3**
Used reasonable voice expression?	**N/A**	**1**	**2**	**3**
Kept participant focused on the interview.	**N/A**	**1**	**2**	**3**
Used appropriate vocabulary.	**N/A**	**1**	**2**	**3**
Established rapport with participant	**N/A**	**1**	**2**	**3**
General Overall Rating	**N/A**	**1**	**2**	**3**

Comments: _____

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Corrective action taken:_____

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Evaluator Signature _____

JHS Self-Administered Questionnaire Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Interviewer Name/ID: ☐

Supervisor Name/ID: ☐

Interview/form reviewed:

Approach to Life ☐ **Hassles and Moods** ☐ **Informed Consent** ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page.

Key: N/A – Not applicable
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Answers participant's questions and concerns.	**N/A**	**1**	**2**	**3**	**4**	**5**
Speaks slowly and distinctly reading the script of the Instructions to the participants at neutral but expressive) and even pace.	**N/A**	**1**	**2**	**3**	**4**	**5**
Reads script of instructions as written.	**N/A**	**1**	**2**	**3**	**4**	**5**
Completes the editing process and reviews forms.	**N/A**	**1**	**2**	**3**	**4**	**5**
General Overall Rating	**N/A**	**1**	**2**	**3**	**4**	**5**

Comments: _____
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Corrective action taken:_____
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Supervisor / Site Visitor Signature
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JHS Self-Administered Questionnaire Supervisor / Site Visit Checklist

DATE: ☐☐ ☐☐ ☐☐ (Mo Day Year)

Interviewer Name/ID: ☐

Supervisor Name/ID: ☐

Interview/form reviewed:

24-hour Physical Activity ☐ **24-hour ABPM** ☐ **24 Hour Urine** ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page.

Key: N/A – Not applicable
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Answers participant's questions and concerns.	**N/A**	**1**	**2**	**3**	**4**	**5**
Speaks slowly and distinctly reading the script of the instructions to the participants at neutral (but expressive) and even pace.	**N/A**	**1**	**2**	**3**	**4**	**5**
Reads script of instructions as written.	**N/A**	**1**	**2**	**3**	**4**	**5**
Completes the editing process and reviews forms.	**N/A**	**1**	**2**	**3**	**4**	**5**
General Overall Rating	**N/A**	**1**	**2**	**3**	**4**	**5**

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature _____

JHS Anthropometry Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Measurements:

Weight ☐ **Height** ☐ **Girth-Waist** ☐ **Girth-Neck** ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if the procedure was carried out correctly by technician Please note any comments or remedial action taken in 'Comments' section if the procedure was carried out correctly. Items are presented in the sequence of the examination procedure, but may require confirmation before or after examination.

Weight Measurements:

1. ☐ Thoroughly explains the procedure to the participant.
2. ☐ Scale is positioned at zero.
3. ☐ Participant is wearing light gown or scrubs, no shoes.
4. ☐ Participant's feet are both flat on the scale.
5. ☐ The measurement is recorded, rounding down to the nearest tenth of a kilogram (kg).

Height Measurements:

6. ☐ Thoroughly explains the procedure to participant.
7. ☐ Participant is standing erect with his/her back to the ruler with heals together.
8. ☐ Participant faces straight ahead
9. ☐ Examiner's eyes are level with the point of measurement.
10. ☐ Reads and records the measurement to the nearest cm.

Girth-Waist Measurements:

11. ☐ Thoroughly explains the procedure to participant.
12. ☐ Participant is standing erect and facing straight ahead, arms hanging loosely at sides and both feet flat on the floor and six inches apart.
13. ☐ The tape is applied at the level of the umbilicus, and participant is instructed to breathe quietly.
14. ☐ The tape is snug but not tight.
15. ☐ The recorder verifies through viewing in full length mirror, that the participant is standing erect and the tape is horizontal.
16. ☐ The measurement is recorded to the nearest cm.

Girth-Neck Measurements:

17. ☐ Thoroughly explains the procedure to participant.
18. ☐ Participant is standing erect, hands at sides, and looking straight ahead.
19. ☐ Technician stands to the side of the participant, on a footstool if necessary to view at the level of the point of measurement.
20. ☐ Participant is asked to swallowed, two figures placed on Adams apple and slight depression felt.
21. ☐ Tape measure placed in proper position.
22. ☐ Neck measurement is read, rounding down to the nearest cm.

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor

Signature_____

JHS Sitting Blood Pressure Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID:

Supervisor Name/ID:

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Throughout Exam:

1. ☐ Measures arm for correct cuff size.
2. ☐ Palpates brachial artery
3. ☐ Marks pulse point.
4. ☐ Wraps cuff center of bladder over brachial pulse.
5. ☐ Leaves Instructs on Posture.
6. ☐ Full five minutes for rest allowed.
7. ☐ Places Work station free of excessive noise Explanation.
8. ☐ Count radial pulse 30 seconds, record reading.
9. ☐ Finds Pulse obliteration point using standard manometer.
10. ☐ Calculates peak inflation, standard manometer.
11. ☐ Calculates peak inflation, R-Z.
12. ☐ If computer is down use the formula (pulse obliteration pressure + R-Z maximum zero number + 30 Explanation.
13. ☐ Connects R-Z tube to cuff.
14. ☐ Sure reservoir lever open (newer devices have no lever).
15. ☐ Opens bellows valve and waits full 3 seconds for mercury to settle.
16. ☐ Obtains Turns thumb wheel (down strokes only).
17. ☐ Places stethoscope in ears.
18. ☐ Inflates rapidly to R-Z peak.
19. ☐ Counts full 5 seconds with pressure steady.
20. ☐ Closes bellows knob.
21. ☐ Places bell on brachial pulse.
22. ☐ Deflates cuff 2 mmHg per second.
23. ☐ Deflates cuff after 2 absent sounds.
24. ☐ Records readings.
25. ☐ Disconnects tubes.
26. ☐ Reads zero value.
27. ☐ Subtracts zero value from <u>each</u> BP reading, if using paper form.
28. ☐ Instructs to hold arm vertical for full 5 seconds.
29. ☐ Waits at least 30 seconds before proceeding.
30. ☐ Repeats R-Z readings.
31. ☐ Informs participant of average readings.

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature_____

JHS Ambulatory Blood Pressure Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID:

Supervisor Name/ID:

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Adequately program the monitor.
2. ☐ Provide instructions for wearing monitor and review Participant Instruction Handout.
3. ☐ Instructed participant in application and removal of monitor.
4. ☐ Apply monitor appropriately sized cuff to non-dominant arm (if non-dominant arm isn't used, document).
5. ☐ Obtain five (5) valid correlation readings using T-tube connector.
6. ☐ Manually initiated first ABP monitor reading.
7. ☐ Recite minimum quality control criteria (within QC grey areas)..

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature_____

JHS Supine ABI Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID:

Supervisor Name/ID:

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

General:

1. ☐ Thoroughly explains the procedure to the participant.
2. ☐ Insures that the participant is relaxed and lying completely supine (legs straight and down with feet rolled outward) on the examination table.
3. ☐ Has participant rest quietly for at least 5 minutes prior to the procedure.
4. ☐ Informs participant just before inflating cuff to avoid startling the participant.

Recognized the following as exclusion criteria:

5. ☐ Participants with venous stasis ulceration or other pathology that precludes placing a BP cuff around the ankle (e.g. open wounds).
6. ☐ Participants with rigid arteries such that an occlusion pressure cannot be reached. If the artery cannot be occluded before the mercury column reaches 300 mmHg, the participant is excluded.
7. ☐ Participants with bilateral amputations of legs.
8. ☐ Participants who fit any of the above categories are recorded as missing data.
9. ☐ If a subject has undergone a mastectomy of the right breast or has other reasons to omit right arm pressures, the left arm will be used for measures.

Arm Brachial Artery Right Arm, unless Exclusions:

10. ☐ Places blood pressure cuff of appropriate size over right brachial artery.
11. ☐ Locates brachial artery by palpation.
12. ☐ Applies ultrasound jelly over brachial artery.
13. ☐ Locates brachial artery using Doppler probe.
14. ☐ Determine Maximal Inflation Level.
15. ☐ Inflates cuff quickly to at least 30 mm Hg above maximal systolic pressure.
16. ☐ Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.
17. ☐ Follow down for 10 mm Hg (two subsequent beats should be heard).
18. ☐ Read and record SBP at eyes level.
19. ☐ Deflates cuff quickly and completely after measurement is obtained.

Right Posterior Tibial Artery:

20. ☐ Use Doppler Probe if Posterior Tibial is not palpable.
21. ☐ Locates right posterior tibial artery by palpation.
22. ☐ Marks the location of the artery with a black marker.
23. ☐ Applies ultrasound jelly over posterior tibial artery.
24. ☐ Locates right posterior tibial artery using Doppler probe.

25. ☐ Inflates cuff quickly to at least 30 mm Hg above maximal pressure.
26. ☐ Deflates cuff at 2 mm Hg/second until a **sustained** systolic pressure is audible.
27. ☐ Reads (at eye level) follows down for 10 mm Hg (two subsequent beats should be heard).
28. ☐ Deflates cuff quickly and completely after measurement is obtained.

Left Posterior Tibial Artery:

29. ☐ Locates left posterior tibial artery by palpation.
30. ☐ Marks the location of the artery with a black marker.
31. ☐ Applies ultrasound jelly over posterior tibial artery.
32. ☐ Locates left posterior tibial artery using Doppler probe.
33. ☐ Inflates cuff quickly to at least 30 mm Hg above maximal pressure.
34. ☐ Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.
35. ☐ Reads (at eye level) follows down for 10 mm Hg (two subsequent beats should be heard).
36. ☐ Deflates cuff quickly and completely after measurement is obtained.

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature _____

JHS ECG Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

External Evaluator Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician preformed each procedure correctly. Please note any comments or remedial action taken in 'Comments' section if performance of a given procedure was not carried out correctly.

1. ☐ Participant asked to disrobe to waist only if back-opening gown worn.
2. ☐ Participant instructed to lie on the recording bed with arms relaxed at the sides.
3. ☐ Limb leads correctly marked.
4. ☐ Electrode areas wiped with alcohol, then with a gauze pad.
5. ☐ V2 position correctly marked.
6. ☐ V1 position correctly marked.
7. ☐ E point position correctly marked.
8. ☐ V6 position correctly marked using chest square.
9. ☐ E point to V6 measured with tape measure and note on scratch paper.
10. ☐ Participant information entered into the V4 position correctly marked using tape measure.
11. ☐ V3 position correctly marked using a flexible ruler.
12. ☐ V5 position correctly marked using a flexible ruler.
13. ☐ Electrodes applied as in steps 3-6.
14. ☐ Appropriate lead write clipped to each electrode.
15. ☐ MAC PC.
16. ☐ Electrodes and lead wire checked.
17. ☐ Participant asked to relax, lie quietly.
18. ☐ Asks participant to relax and lie quietly.
19. ☐ Electrodes on skin 2-5 minutes before taking ECG.
20. ☐ MAC PC display watched for error messages.
21. ☐ If error message(s): electrode contacts and lead wires checked, display observed again.
22. ☐ If display counts past 45: repeat skin preparation using 2 strokes with fine sandpaper. Replace with electrodes on limb leads first, if necessary replace all electrodes.
23. ☐ ECG tracing removed from MAC PC.
24. ☐ ECG examined for baseline drift, noise, 60-cycle interference and muscle tremor.
25. ☐ When technically inadequate, ECG re-recorded until an acceptable recording is achieved.
26. ☐ Electrodes removed.

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature _____

JHS Venipuncture Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Venipuncture:

1. ☐ Labels checked.
2. ☐ Venipuncture Form filled.
3. ☐ Tourniquet application and release.
4. ☐ Venipuncture technique.
5. ☐ Tube collection sequence.

Handling of filled draw tubes:

6. ☐ Inversion technique.
7. ☐ Tube incubation location.
8. ☐ Stasis obtained.
9. ☐ Needle disposal.
10. ☐ Universal precaution employed.

Comments: _____

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Corrective action taken:_____

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Supervisor / Site Visitor Signature_____

JHS Laboratory Processing, Packing and Shipping Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

External Evaluator @ Central Lab.: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Processing:

1. ☐ Knowledge of centrifuge operation.
2. ☐ Aliquotting supply set-up.
3. ☐ Stage I tube spin.
4. ☐ Stage II aliquotting.
5. ☐ Stage III tube spin.
6. ☐ Final processing stage.
7. ☐ VPT Form completed.
8. ☐ Freezer organization.
9. ☐ Time constraints.
10. ☐ Disposal of contaminated supplies.

Packing and Shipping:

11. ☐ Specimens bagged.
12. ☐ Adequate dry ice used in shipping.
13. ☐ Shipping paperwork.
14. ☐ Complete specimen sets.
15. ☐ Sufficient specimen volumes.
16. ☐ Accurate documentation forms.
17. ☐ Orderly shipments.
18. ☐ Communication of unusual events.

Comments: _____

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Corrective action taken_____

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JHS PFT CERTIFICATION / SUPERVISOR / SITE VISIT CHECKLIST

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

During examination:

1. ☐ Greets participant professionally.
2. ☐ Boots system and enters baseline data in PFT computer.
3. ☐ Teaches participant technique for performing PFT (exhalation only).
4. ☐ Uses clean disinfected tube and disposable mouthpiece for participant.
5. ☐ Equipment at height of 29-30 inches positioned below level of participant's head.
6. ☐ Participant remains seated for test (unless morbidly obese).
7. ☐ Completes 3 acceptable trials (no more than 8 tries).
8. ☐ Instructs participant to relax between trials.
9. ☐ Complete 3 acceptable trials (no more than 5 tries).

Data transmission and quality control (Reading Center Technician QC Report):

10. ☐ Transmits images successfully via computer disc.
11. ☐ Uses proper JHS ID labeling on study form.
12. ☐ Demonstrates understanding of QA procedure and frequency of PFT calibration.
13. ☐ Documents any problems (if they occurred) in obtaining either test.

Comments: _____

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Corrective action taken: _____

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Supervisor / Site Visitor Signature__ _____

JHS Carotid Ultrasound Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

External Evaluator Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

General/Initial Scan:

1. ☐ Completes the Sonographer Log Sheet.
2. ☐ Instructs participant regarding expectations (e.g. talking into tape) for carotid ultrasound.
3. ☐ Positions participant in supine position without head rotation.
4. ☐ Enters proper participant, study, and image annotations.
5. ☐ Locates the bifurcation, distinguishes the internal from the external carotid artery.
6. ☐ Uses color and pulse wave Doppler imaging as identification aids.
7. ☐ Adjusts gain controls to maximize wall and lesion interfaces.

Comments:

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Corrective-action taken:

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Supervisor / Site Visitor

Signature:___ _____ _____

JHS Echocardiogram Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

External Evaluator Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Positioning

1. ☐ Instructs the participant to lay in left lateral position, encouraging the participant to relax, uncross legs, refrain from talking and moving, breath normally. Positions participant on back for some views.
2. ☐ Attach three EKG electrodes for RA, LA and LL on upper chest and abdomen.

Data collection

3. ☐ Records all data at end expiration or inspiration for a time that will encompass 10-20 beats of relevant data.
4. ☐ Obtains 2-D and color doppler mitral and aortic valves data in parasternal long axis view (3rd and 4th intercostal space).
5. ☐ Obtains 2-D and color doppler, M-Mode, pulsed doppler and continuous doppler data in appropriate views (parasternal long axis, parasternal short axis, apical 4 chamber, apical 2 chamber and long axis, and subcostal views.
6. ☐ Removes EKG electrodes and remove any residual ultrasound gel. If blood draw not yet completed, instructs participant to remain supine. Otherwise, assists participant as needed to sit up.

Transferring and Transmitting Data

7. ☐ Digital transfer of data during procedures on a given participant.
8. ☐ Completes Sonographer Worksheet.

Comments:

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Corrective action taken: _____

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Supervisor / External Evaluator Signature

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